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| 10/580,602 | 05/25/2006 | Robert Boizel | MERCK-2822 | 4960 |
| 23599 7590 07/22/2008 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201 | | | | |
| EXAMINER | | | | |
| BLAND, LAYLA D | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/580,602
Filing Date: May 25, 2006
Appellant(s): BOIZEL ET AL.

Csaba Henter
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed May 28, 2008 appealing from the Office action mailed December 28, 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

| | | |
|-------------|--------|---------|
| WO 00/39113 | Brunet | 07-2000 |
| WO 00/47209 | Chen | 08-2000 |

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 8-11, 13-19, 23-25, and 35-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brunet et al (WO 00/39113, published July 6, 2000) in view of Chen et al. (WO 00/47209, published August 17, 2000). This rejection is set forth in the prior Office Action mailed December 28, 2007, and reiterated in full below.

Brunet et al. teach compounds of the same core structure as the instant application. The compounds are powerful activators of the PPAR α and PPAR γ isoforms

and exhibit hypolipidaemic and hypoglycaemic effects [page 2, lines 15-25]. The hypolipidaemic and hypoglycemic effect of the compounds result from their ability to activate the PPAR α and PPAR γ isoforms [page 33, lines 15-17]. Given as an exemplary compound [page 34, lines 12-15] and preferred species [page 10, lines 9 and 10] is Example 16b, (2E, 4E)-5-(3,3-dimethyl-7-methoxy-2,3-dihydrobenzoxepin-5-yl)-3-methylpenta-2,4-dienoic acid, which is the species which applicant has elected in the instant application. To demonstrate the antidiabetic and hypolipidaemic activity of the compounds, mice were treated via oral administration of 100mg/kg/day of the compound of example 16 [page 34, lines 21-26].

Brunet et al. do not teach the treatment of hyperuricemia or associated disorders, or the lowering of the serum uric acid level of a subject.

Chen et al. teach that activators of PPAR γ are uricosuric agents which are useful for the treatment of gout and related disorders [page 2, lines 31-33]. Chen et al. teach methods for the treatment of diseases associated with hyperuricemia (defined by Pittman et al. as a serum uric acid concentration above 7 mg per dL) and methods for modulating serum uric acid levels in a subject [page 3, lines 1-5 and 23-24]. The invention is derived from the discovery that PPAR γ ligands act as hyperuricemic agents [page 8, lines 9-11] and the methods of the invention can be carried out using essentially any PPAR γ ligand [page 9, lines 21-22]. The preferred dosage for administration of a high affinity PPAR γ ligand is in the range of 0.05 mg/kg to about 20 mg/kg, more preferably 0.05 mg/kg to about 2 mg/kg, most preferably 0.05 mg/kg to 0.2

mg/kg per day [page 10, lines 12-15]. Administration may be provided in single or multiple dosages [page 10, lines 19-21].

It would have been obvious to one of ordinary skill in the art to use the compounds of Brunet et al. for the treatment of hyperuricemia and associated disorders. The skilled artisan would have been motivated to do so, and would have reasonably expected success, because Chen et al. teach that activators of PPAR γ are useful for the treatment of gout and related disorders and the compounds of Brunet et al. are taught to be powerful activators of PPAR γ . The exemplary compound of Brunet et al. (elected species in the instant application) meets the limitations of claims 1-6, 8-11, 13-25, and 35-37.

(10) Response to Argument

Appellant argues that the compounds taught by Brunet et al. activate both PPAR γ and PPAR α , and that the skilled artisan would not expect dual activators (those which activate both PPAR γ and PPAR α) to be effective to treat indications associated with activity at PPAR γ . Appellant's argument is not found persuasive. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. In re Keller, 642 F.2d 413, 208 SPQ 871 (CCPA 1981); In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See MPEP 2145.

In this case Chen has been cited by the examiner primarily for its clear teaching that activators of PPAR γ act as hyperuricemic agents and the compounds taught by Brunet et al. are powerful activators of PPAR γ . Thus, the skilled artisan would have a

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reasonable expectation that Brunet's compounds would be useful for treating hyperuricemia and associated disorders. The assertion that Brunet's compounds may also have other activity does not negate Chen's teaching that compounds which activate PPAR γ can be used for the treatment of hyperuricemia and related disorders.

The claimed invention is clearly obvious in view of the prior art.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Layla Bland/

Examiner, Art Unit 1623

Conferees:

/Shaojia Anna Jiang, Ph.D./

Supervisory Patent Examiner, Art Unit 1623

/Leigh C. Maier/

Primary Examiner, Art Unit 1623

